Bicillin® L-A

(penicillin G benzathine injectable suspension)

TUBEX® 1 mL and 2 mL

for deep IM injection only

warning, not for intravenous use, do not inject

WARNING: NOT FOR INTRAVENOUS USE. DO NOT INJECT INTRAVENOUSLY OR ADMIX WITH OTHER INTRAVENOUS SOLUTIONS. THERE HAVE BEEN REPORTS OF INADVERTENT INTRAVENOUS ADMINIS-TRATION OF PENICILLIN G BENZATHINE WHICH HAS BEEN ASSOCIATED WITH CARDIORESPIRATORY ARREST AND DEATH. Prior to administration of this drug, carefully read the WARNINGS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION sections of the labeling.

Rx Only

DESCRIPTION

Bicillin L-A (penicillin G benzathine injectable suspension) is available for deep intramuscular injection. Prnicillin G benzathin is prepared by the reaction of dibenzylethylene diamine with two molecules of penicillos. It is chemically designated as (25,6,6,6,3-3.0)methyl-7-coo-6-[2-phenylacetamido)-4-thia-1-azabicy-clo[3.2.0]heptane-2-carboxylic acid compound with N,N'-dibenzylethylenediamine (2:1), tetrahydrate. It occurs as a white, crystalline powder and is very slightly soluble in water and sparingly soluble in alcohol. Its chemical structure is as follows:

Bicillin L-A contains penicillin G benzathine in aqueous suspension with sodium citrate buffer and, as w/v. imately 0.5% lecithin, 0.6% carboxymethylcellulose, 0.6% povidone, 0.1% methylparaben, and

Bicillin L-A injectable suspension in TUBEX® formulation is viscous and opaque. It is available in 1 mL and 2 mL TUBEX® Sterile Cartridge-Needle Units containing the equivalent of 600,000 units and 1,200,000 units respectively of penicillin 6 as the benzathine salt. Read CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections prior to use.

CLINICAL PHARMACOLOGY

General

Penicillin G benzathine has an extremely low solubility and, thus, the drug is slowly released from intramus-cular injection sites. The drug is hydrolyzed to penicillin G. This combination of hydrolysis and slow absorption results in blood serum levels much lower but much more prolonged than other parenteral penicillins.

Intramuscular administration of 300,000 units of penicillin G benzathine in adults results in blood levels of 0.03 to 0.05 units per mL, which are maintained for 4 to 5 days. Similar blood levels may persist for 10 days following administration of 600,000 units and for 14 days following administration of 1,200,000 units. Blood concentrations of 0.003 units per mL may still be detectable 4 weeks following administration of 1.200.000 units.

Approximately 60% of penicillin G is bound to serum protein. The drug is distributed throughout the body tissues in widely varying amounts. Highest levels are found in the kidneys with lesser amounts in the liver, skin, and intestines. Penicillin 6 penetrates into all other tissues and the spinal fluid to a lesser degree. With normal kidney function, the drug is excreted rapidly by tubular excretion. In neonates and young infants and in individuals with impaired kidney function, excretion is considerably delayed.

Penicillin G exerts a bactericidal action against penicillin-susceptible microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell-wall mucopeptide. It is not active against the penicillinase-producing bacteria, which include many strains of staphylococci.

The following *in vitro* data are available, but their clinical significance is unknown. Penicillin G exerts high vitro activity against staphylococci (except penicillinase-producing strains), streptococci (Groups A, C, G, H, L, and M), and pneumococci. Other organisms susceptible to penicillin G are Neisseria gonorrhoeae, Corvnebacterium diphtheriae. Bacillus anthracis. Clostridia species, Actinomyces boyis. Streptobacillus monil-Itormis, Listeria monocytogenes, and Leptospira species. Treponema pallidum is extremely susceptible to the bactericidal action of penicillin G.

Susceptibility Test: If the Kirby-Bauer method of disc susceptibility is used, a 20-unit penicillin disc should give a zone greater than 28 mm when tested against a penicillin-susceptible bacterial strain.

INDICATIONS AND USAGE

Intramuscular penicillin G benzathine is indicated in the treatment of infections due to penicillin-G-sensitive microorganisms that are susceptible to the low and very prolonged serum levels common to this particular dosage form. Therapy should be guided by bacteriological studies (including sensitivity tests) and by clinical

The following infections will usually respond to adequate dosage of intramuscular penicillin G benzathine: Mild-to-moderate infections of the upper-respiratory tract due to susceptible streptococci

Venereal infections - Syphilis, yaws, bejel, and pinta.

Medical Conditions in which Penicillin G Benzathine Therapy is indicated as Prophylaxis:

Rheumatic fever and/or chorea – Prophylaxis with penicillin G benzathine has proven effective in preventing recurrence of these conditions. It has also been used as follow-up prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.

CONTRAINDICATIONS

A history of a previous hypersensitivity reaction to any of the penicillins is a contraindication.

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Penicillin G benzathine should only be prescribed for the indications listed in this insert

SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTIC) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH IN PATIENTS ON PENICILLIN HERAPY. THESE REACTIONS ARE MORE LIRELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HERAPY. THESE REACTIONS ARE MORE LIRELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF SENSITIVITY OF MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH BICILLIN L-A CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS OR OTHER ALLERGENS. IF AN ALLERGIC REACTION OCCURS. BICILLIN L-A SHOULD BE DISCONTINUED AND APPROPRIATE THERAPY INSTITUTED. SERIOUS ANAPHYLAG-TIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN, INTRAVENOUS STEROIDS AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE

Pseudomembranous Colitis

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including peni-cillin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of any

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-

After the diagnosis of pseudomembranous colitis has been established, appropriate therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

Do not inject into or near an artery or nerve

Injection into or near a nerve may result in permanent neurological damage

Inadvertent intravascular administration, including inadvertent direct intra-arterial injection or injection immediately adjacent to arteries, of Bicillin L-A and other penicillin preparations has resulted in severe neurovascular damage, including transverse myelitis with permanent paralysis, gangrene requiring amputaineutovascular duringer, including universe interior and per line in the per landerit planalysis, gardierie requiring airiputation of digits and more proximal portions of extremities, and necrosis and sloughing at and surrounding the injection site. Such severe effects have been reported following injections into the buttock, thigh and deltoid areas. Other serious complications of suspected intravascular administration which have been reported include immediate pallor, mottling, or cyanosis of the extremity both distal and proximal to the injection site, followed by bleb formation; severe edema requiring anterior and/or posterior compartment fasciotomy in the lower extremity. The above-described severe effects and complications have most often occurred in infants and amplifying Department of the provided provided and the provided provide and small children. Prompt consultation with an appropriate specialist is indicated if any evidence of compromise of the blood supply occurs at, proximal to, or distal to the site of injection. 1-9 (See CONTRAINDICATIONS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections.)

Do not inject intravenously or admix with other intravenous solutions. There have been reports of nt intravenous administration of penicillin G benzathine which has been associated with car diorespiratory arrest and death. (See DOSAGE AND ADMINISTRATION section.)

Quadriceps femoris fibrosis and atrophy have been reported following repeated inframuscular injections of penicillin preparations into the anterolateral thigh.

Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma

Care should be taken to avoid intravenous or intra-arterial administration, or injection into or near major peripheral nerves or blood vessels, since such injection may produce neurovascular damage. (See WARN-INGS, and DOSAGE AND ADMINISTRATION sections.)

Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms, including fungi Should superinfection occur, appropriate measures should be taken.

In streptococcal infections, therapy must be sufficient to eliminate the organism; otherwise, the sequelae of streptococcal disease may occur. Cultures should be taken following completion of treatment to determine whether streptococci have been eradicated.

Drug Interactions

Tetracycline, a bacteriostatic antibiotic, may antagonize the bactericidal effect of penicillin, and concurrent use of these drugs should be avoided.

Concurrent administration of penicillin and probenecid increases and prolongs serum penicillin levels by decreasing the apparent volume of distribution and slowing the rate of excretion by competitively inhibiting renal tubular secretion of penicillin.

Pregnancy Category B

Reproduction studies performed in the mouse, rat, and rabbit have revealed no evidence of impaired fertility or harm to the fetus due to penicillin G. Human experience with the penicillins during pregnancy has no shown any positive evidence of adverse effects on the fetus. There are, however, no adequate and well-controlled studies in pregnant women showing conclusively that harmful effects of these drugs on the fetus can be excluded. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Soluble penicillin G is excreted in breast milk. Caution should be exercised when penicillin G benzathine administered to a nursing woman.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been conducted with this drug.

(See INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION sections.)

Geriatric Use

Clinical studies of penicillin G benzathine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function (see CLINICAL PHARMACOLOGY). Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

As with other penicillins, untoward reactions of the sensitivity phenomena are likely to occur, particularly in individuals who have previously demonstrated hypersensitivity to penicillins or in those with a history of allergy, asthma, hay fever, or urticaria.

As with other treatments for syphilis, the Jarisch-Herxheimer reaction has been reported

The following have been reported with parenteral penicillin G:

General: Hypersensitivity reactions including the following: skin eruptions (maculopapular to exfoliative dermatitis), urticaria, laryngeal edema, fever, eosinophilia; other serum sickness-like reactions (including chills, fever, edema, arthralgia, and prostration); and anaphylaxis including shock and death. Note Urticaria, other skin rashes, and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, penicillin G should be discontinued unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to therapy with penicillin G. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

Gastrointestinal: Pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment. (See WARNINGS section.)

Hematologic: Hemolytic anemia, leukopenia, thrombocytopenia

Neurologic: Neuropathy

The following adverse events have been temporally associated with parenteral administration of penicillin G benzathine:

Body as a Whole: Hypersensitivity reactions including allergic vasculitis, pruritis, fatigue, asthenia, and pain aggravation of existing disorder; headache.

Cardiovascular: Cardiac arrest; hypotension; tachycardia; palpitations; pulmonary hypertension; pulmonary embolism; vasodilation; vasovagal reaction; cerebrovascular accident; syncope.

Gastrointestinal: Nausea, vomiting; blood in stool; intestinal necrosis

Hemic and Lymphatic: Lymphadenopathy.

Injection Site: Injection site reactions including pain, inflammation, lump, abscess, necrosis, edema, hemore rhage, cellulitis, hypersensitivity, atrophy, ecchymosis, and skin ulcer. Neurovascular reactions including warmth, vasospas m, pallor, mottling, gangrene, numbness of the extremities, cyanosis of the extremities and neurovascular damage

Metabolic: Elevated BUN, creatinine, and SGOT.

Musculoskeletal: Joint disorder, periostitis; exacerbation of arthritis; myoglobinuria; rhabdomyolysis.

Nervous System: Nervousness; tremors; dizziness; somnolence; confusion; anxiety; euphoria; transverse myellits; seizures; coma. A syndrome manifested by a variety of CNS symptoms such as severe agitation with confusion, visual and auditory hallucinations, and a fear of impending death (holinge's syndrom), has been reported after administration of penicillin G procaine and, less commonly, after injection of the combination of penicillin G benzathine and penicillin G procaine. Other symptoms associated with this syndrome, such as psychosis, seizures, dizziness, tinnitus, cyanosis, palpitations, tachycardia, and/or abnormal perception in taste, also may occur.

Respiratory: Hypoxia; apnea; dyspnea.

Skin: Diaphoresis

Special Senses: Blurred vision: blindness. Urogenital: Neurogenic bladder; hematuria; proteinuria; renal failure; impotence; priapism.

OVERDOSAGE

Penicillin in overdosage has the potential to cause neuromuscular hyperirritability or convulsive seizures

DOSAGE AND ADMINISTRATION Streptococcal (Group A) Upper-respiratory Infections (for example, pharyngitis)

Adults - single injection of 1,200,000 units; older pediatric patients - single injection of 900,000 units; infants and pediatric patients under 60 lbs. - 300,000 to 600,000 units.

Syphilis

2,400,000 units (1 dose). Late (tertiary and neurosyphilis) – 2,400,000 units at 7-day intervals for three doses

Bicillin LA 1 and 2 mL CI 4656-6 Rev. 07/23/04 Wyeth Drawing #5881 Printer to Insert Actual Pharma Code (492) Congenital - under 2 years of age: 50,000 units/kg/body weight; ages 2 to 12 years: adjust dosage based on

Yaws, Beiel, and Pinta - 1,200,000 units (1 injection).

Prophylaxis – for rheumatic fever and glomerulonephritis.

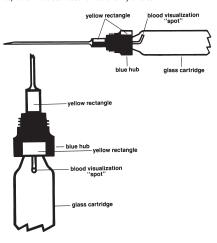
Following an acute attack, penicillin G benzathine (parenteral) may be given in doses of 1,200,000 units once a month or 600,000 units every 2 weeks.

Method of Administration

Bicillin L-A is intended for Intramuscular Injection ONLY. Do not inject into or near an artery or nerve, or intravenously or admix with other intravenous solutions. (See WARNINGS section).

Administer by DEEP INTRAMUSCULAR INJECTION in the upper, outer quadrant of the buttock. In neonate infants and small children, the midlateral aspect of the thigh may be preferable. When doses are repeated, vary the injection site.

The TUBEX® cartridge for this product incorporates several features that are designed to facilitate the visualization of blood on aspiration if a blood vessel is inadvertently entered.



The design of this cartridge is such that blood which enters its needle will be quickly visualized as a red or dark-colored "spot." This "spot" will appear on the barrel of the glass cartridge immediately proximal to the blue hub. The TUBEX is designed with two orientation marks, in order to determine where this "spot" can be seen. First insert and secure the cartridge in the TUBEX injector in the usual fashion. Locate the yellow rectangle at the base of the blue hub. This yellow rectangle is aligned with the blood visualization "spot" An imaginary straight line, drawn from this yellow rectangle to the shoulder of the glass cartridge, will point to the area on the cartridge where the "spot" can be visualized. When the needle cover is removed, a second yellow rectangle will be visible. The second yellow rectangle is also aligned with the blood visualization "spot" to assist the operator in locating this "spot." If the 2 mL metal or plastic syringe is used, the glass cartridge should be rotated by turning the plunger of the syringe clockwise until the yellow rectangle is also should be rotated by turning the plunger of the syringe clockwise until the yellow rectangle is discoultized. visualized. If the 1 mL metal syringe is used, it will not be possible to continue to rotate the glass cartridge visualization in the limited syngle's user, it will not be possible to commune to idea the glass calting clockwise once it is properly engaged and fully threaded; it can, however, then be rotated counterclockwise as far as necessary to properly orient the yellow rectangles and locate the observation area. (In this same area in some cartridges, a dark spot may sometimes be visualized prior to injection. This is the proximal end of the needle and does not represent a foreign body in, or other abnormality of, the suspension.)

Thus, before the needle is inserted into the selected muscle, it is important for the operator to orient the yellow rectangles so that any blood which may enter after needle insertion and during aspiration can be visualized in the area on the cartridge where it will appear and not be obscured by any obstructions.

After selection of the proper site and insertion of the needle into the selected muscle, aspirate by pulling back on the plunger. While maintaining negative pressure for 2 to 3 seconds, carefully observe the barrel cartridge in the area previously identified (see above) for the appearance of a red or dark-colored "spot.

Blood or "typical blood color" may *not* be seen if a blood vessel has been entered — only a mixture of blood and Bicillin L-A. The appearance of any discoloration is reason to withdraw the needle and discard the glass **TUBEX** cartridge. If it is elected to inject at another site, a new cartridge should be used. If no blood or discoloration appears, inject the contents of the cartridge slowly. Discontinue delivery of the dose if the subject complains of severe immediate pain at the injection site or if, especially in neonates, infants and young children, symptoms or signs occur suggesting onset of severe pain.

Some TUBEX cartridges may contain a small air bubble which should be disregarded, since it does not affect administration of the product. DO NOT clear any air bubbles from the cartridge or needle as this may interfere with the visualization of any blood or discoloration during aspiration.

Because of the high concentration of suspended material in this product, the needle may be blocked if the injection is not made at a slow, steady rate.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to admin

istration, whenever solution and container permit. HOW SUPPI IFN

Bicillin® L-A (penicillin G benzathine suspension) is supplied in packages of 10 TUBEX® Sterile Cartridge-Needle Units as follows

1 mL size, containing 600,000 units per TUBEX®, (21 gauge, thin-wall 1 inch needle for pediatric use), NDC 61570-146-10.

2 mL size, containing 1,200,000 units per TUBEX®, (21 gauge, thin-wall 1-1/4 inch needle), NDC 61570-147-10. Store in a refrigerator, 2° to 8°C (36° to 46°F).

Keep from freezing.

Bicillin L-A (penicillin G benzathine suspension) is also available in packages of 10 disposable syringes as follows 4 mL size, containing 2,400,000 units per syringe (18 gauge x 2 inch needle), NDC 61570-148-10.

PLEASE NOTE: THE METAL TUBEX HYPODERMIC SYRINGE AND TUBEX **FAST-TRAK SYRINGE HAVE BEEN** DISCONTINUED AND REPLACED BY
THE TUBEX INJECTOR.
EXCHANGE OF THESE DISCONTINUED
SYRINGES IS AVAILABLE, FREE OF SYRINGES IS AVAILABLE, FREE OF CHARGE, FROM WYETH-AYERST DIRECTLY. FOR LOADING AND UNLOADING INFORMATION ON THESE DISCONTINUED SYRINGES, CONTACT THE MEDICAL AFFAIRS DEPARTMENT AT WYETH-AYERST LABORATORIES, P.O. BOX 8299, PHILADELPHIA, PA 19101.

TUBEX® Injector NOTE: The TUBEX Injector is REUSABLE: do not discard.

DIRECTIONS FOR USE: BEFORE PROCEEDING, SEE IMPORTANT INFORMATION UNDER DOSAGE AND ADMINISTRATION SECTION.



NOTE: USE ASEPTIC TECHNIQUE FOR ALL MANIPULATIONS OF STERILE PARTS.

To load a TUBEX Sterile CLOSE OPEN Cartridge-Needle Unit into the TUBEX Injector

1. Turn the ribbed collar to the "OPEN" position until it



3. Thread the plunger rod into the plunger of the **TUBEX** Sterile Cartridge-Needle Unit until slight resistance is felt

The Injector is now ready for use in the usual manner.



To load an E.S.I. DOSETTE® Sterile Cartridge-Needle Unit into the TUBEX Injector

. Turn the ribbed collar to ne "OPEN" position until stops



3. Thread the plunger rod into the plunger of the E.S.I. **DOSETTE** Sterile Cartridge-Needle Unit until slight resistance is felt.

4. Engage the needle-cap assembly by pulling the cap down over the silver cartridge hub. The needle is fully engaged when the silver hub is completely covered. The Injector is now ready for use in the usual manner.

To administer TUBEX/DOSETTE Sterile

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To administer TUBEX/DOSETTE Sterile Cartridge-Needle Units Method of administration is the same as with conventional syringe. Remove needle cover by grasping it securely; twist and pull. Introduce needle into patient, aspirate by pulling back slightly on the plunger, and inject.

To remove the empty TUBEX/DOSETTE Cartridge-Needle Unit and dispose into a vertical needle disposal

1. Do not recap the needle Disengage the plunger rod.

2. Hold the Injector, needle down, over a vertical needle disposal container and



3. Discard the needle cover

To remove the empty TUBEX/DOSETTE Cartridge-Needle Unit and dispose into a horizontal (mailbox) needle disposal container

- 1. Do not recap the needle. Disengage the plunger rod.
- 2. Open the horizontal (mailbox) needle disposal container. Insert
 TUBEX/DOSETTE Cartridge-Needle Unit. needle pointing down, halfway into container. Close the container lid on cartridge. Loosen ribbed collar; TUBEX/DOSETTE Cartridge-Needle Unit

will drop into the container.

3. Discard the needle cover The **TUBEX** Injector is reusable and should not be discarded.

Used TUBEX/DOSETTE Cartridge-Needle Units should not be employed for successive injections or as multiple-dose containers. They are included and only once and discarded.

NOTE: Any graduated markings on TUBEX/DOSETTE Sterile Cartridge Needle Units are to be used only as a guide in administering doses.

Wyeth-Ayerst does not recommend and will not accept responsibility for the use of any cartridge-needle units other than TUBEX or E.S.I. DOSETTE Cartridge-Needle Units in the TUBEX

TUBEX is a registered trademark of Wyeth-Ayerst Laboratories.

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